REMARKS

Claims 1-3, 6-22, and 24-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Vaillancourt (U.S. Patent 4,798,597) alone or in view of Kitou et al. (U.S. Patent 5,993,436). The rejection is respectfully traversed below, and the Examiner is requested to reconsider and allow the claims.

The reference Vaillancourt teaches a two layer intubation tube having an outer layer of polyurethane and an inner layer of a hydrophilic polyurethane having glycol chains. The outer layer of Vaillancourt is made from a soft polyurethane having a hardness of from 60-80 Shore A. By contrast, the present invention has a hard layer with a hardness of from 95A to 85D shore hardness. Polyether polyurethanes having the hardness of Vaillancourt's outer layer are tacky and can present the problems discussed in Applicants' specification and the problems are solved by Applicants' invention.

The inner layer of Vaillancourt is a very different polyurethane than that disclosed in the present invention. Vaillancourt does not disclose the specifics of the chemistry in preparing the inner layer. Vaillancourt identifies the inner layer as a polyurethane containing glycol chains to render the inner layer hydrophilic. The inner layer polymer was supplied by Tyndale Plains-Hunter as D-2. Applicants searched for patents by Tyndale Plains-Hunter and have found several directed to hydrophilic polymers, but cannot be certain as to which polymer might have been used by Vaillancourt as the inner layer. From Vaillancourt's disclosure, one can conclude that the inner layer is not a typical polyurethane. When placed in contact with water, the inner layer of Vaillancourt swells and becomes very soft. The two-layer tube of Vaillancourt, upon exposure to water becomes like a "wet noodle", as stated in col. 2, line 54.

Although one cannot be certain of the structure of the inner layer of Vaillancourt, from the literature, it appears to have long chains of glycol groups, with many groups along the polymer chain which are able to attract and hold water.

Applicants' polyurethane layers have a glycol component in the polymer, but the glycol is the chain extender and along with the isocyanate forms the hard segment of the polyurethane. Polyurethanes, such as those used by Applicants, will not absorb great quantities of water and swell to the point of becoming very soft.

The Examiner is incorrect in the assumption that the degree of hardness of a layer can be determined by adjusting parameters, such as thickness. While the tube would be more flexible if it were thinner, the thickness has nothing to do with the hardness of the polymers used in the tube. The hardness of the polymers is measured according to ASTM D2240 (as specified in the claims) and is not dependent on the thickness of the layers in the tube. A thinner tube would be more flexible, but would not change in hardness.

In summary, the Vaillancourt reference taken alone does not render the present invention obvious. The hardness of the polyether polyurethane layer used in Vaillancourt is much softer than the hard layer used by Applicants. Also, the inner layer of Vaillancourt is a very different (hydrophilic) material than that used in either layer of the tube of this invention. One skilled in the art of making medical tubing would not be led to the invention as claimed by Applicants from the teachings of Vaillancourt.

The reference Kitou et al. teaches an indwelling catheter made from a hard polycaprolactone polyurethane having a hardness of 60D or more. The catheter tube of Kitou is a single layer tube which can have strips of x-ray-opaque agent embedded in the tube (see Fig. 2). Kitou states at col. 2, lines 54-55, that the preferred isocyanate is an aromatic diisocyanate (diphenylmethane-4,4'-diisocyanate). Kitou does disclose that aliphatic isocyanates can be used but that aromatics are preferred. Also, Kitou used aromatic isocyanate in the examples. Applicants' claims are limited to aliphatic polyurethanes, thus the use of aromatic isocyanates are excluded.

The hardness of the polyurethane used by Kitou does overlap the range of hardness for the hard layer claimed by Applicants, but Kitou is a single layer tube and prefers aromatic isocyanates.

From the combined teachings of Vaillancourt and Kitou, one skilled in the art could conclude that the preferred aromatic polyurethane of Kitou could be used in the outer layer of Vaillancourt. The preferred aromatic polyurethane of Kitou could not be used in the inner layer of Vaillancourt as it does not have the hydrophilic properties required by the inner layer of Vaillancourt (see Kitou Abstract where there is only a small reduction in modulus if Kitou's

polyurethane when exposed to warm water). The outer layer of Vaillancourt could not be used in Kitou as it is too soft and would kink.

In summary, the combined teachings of Vaillancourt and Kitou do not teach the invention as recited in Applicants' claims. Applicants require an aliphatic polyurethane, unlike Kitou, and Applicants require a hardness range outside of that disclosed by Vaillancourt. The claims in the present application are unobvious when the teachings of Vaillancourt are considered in view of Kitou.

The rejection has been traversed and the Examiner is requested to reconsider and allow the present claims.

Respectfully submitted,

By Joe A. Powell
Joe A. Powell
Attorney for Applicants
Reg. No. 28,108

Noveon IP Holdings Corp.
9911 Brecksville Road
Cleveland, Ohio 44141-3247
Ph: (216) 447-5716
Fax: (216) 447-5933

Date: February 21, 2006
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